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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/800,200	03/11/2004	Klaus Breddam	12845.0009US01	9044

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EXAMINER

IBRAHIM, MEDINA AHMED

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 10/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary**Application No.**

10/800,200

Applicant(s)

BREDDAM ET AL.

Examiner

Medina A. Ibrahim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) 15-47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14, 48 and 49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election of Group I, claims 1-14 and 48-49 in the reply filed on 09/11/06 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Applicant asserts that claim 1 is a linking claim, linking the barley plant of Group I with the products of claims 15-41 and 45-47 produced from the barley plants and with the methods of producing the barley plants of claims 42-44. Examiner respectfully disagrees. MPEP 809 states "[L]inking claims and the inventions they link together are usually either all directed to products or all directed to processes (i.e., a product claim linking properly divisible product inventions, or a process claim linking properly divisible process inventions). The MPEP further states that the most common types of linking claims are (A) genus claims linking species claims; and (B) subcombination claims linking plural combinations. However, the invention of Group I does not define genus claims linking species claims nor it defines subcombination claims linking plural combinations. In addition, the coexamination of the invention of Group I with any of the other two groups would present search burden, for the reasons set forth in the restriction requirement of 09/11/06.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6, 9, and 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rutgersson et al (Enzymes (1997), Vol. 74 (6), pp. 727-732) in view of Kleinhofs et al (Mutations Research (1978) 51:29-35).

The claim are drawn to a barley plant or a part thereof, comprising less than 5% of LOX-1 activity of a wild-type barley or comprises less than 1% of the LOX-1 protein as compared to a wild-type barley plant, wherein the part is kernel; said barley plant or part thereof produced by the method steps as listed in the claim 5. The claims are also drawn to said barley plant or part thereof, wherein the gene encoding LOX-1 contains a premature nonsense codon or splice site mutation.

Rutgersson et al teach a process to inactivate lipoxygenase in barley cultivar Blenheim. Rutgersson teaches total lipoxygenase inactivation with less 20% remaining activity was obtained. Rutgersson et al teach that low lipoxygenase activity in barley is

desirable because it improves oxidative stability of cereal product, and that lipoxygenase is the main factor in off-flavor production in malt.

Rutgersson et al do not explicitly teach a barley plant with less than 5% LOX1 activity of the wild-type barley.

Kleinhofs et al teach barley mutants with single gene mutation and methods for generating said plants. Kleinhofs et al teach waxy endosperm mutants that occurred at high frequency in barley using sodium azide to induce the mutation. Because specific gene or function mutations occur with high frequency in azide-mutagenized barley, Kleinhofs et al suggest that the method can be used to produce barley mutants with a desired gene mutation/loss of function.

Therefore, it would have been obvious to one of ordinary skill in the art at the time this application was filed to use the method of inactivating lipoxygenase in barley as taught by Rutgersson, and to modify that method by incorporating the use of sodium azide to induce stable LOX mutation/loss of function in barley to produce barley LOX mutant with complete loss of LOX function with a reasonable expectation of success, given the high frequency single gene function/ mutations occurrence in azide-mutagenized barley as taught by Kleinhofs et al. One would have been motivated to produce barley plants having reduced or with no Lox-activity, given that low or no lipoxygenase activity in barley improves oxidative stability of cereal product, and given that lipoxygenase is the main factor in off-flavor production in malt as taught by Rutgersson et al. Therefore, the invention as whole was a prima facie obvious.

Claim Rejections - 35 USC § 103

Claims 1-14 and 48-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Douma et al (WO 02/053721).

Douma et al teach barley cultivars having greatly reduced lipoxygenase-1 activity (figure 16). The barley plants contain a mutant lox-1 gene expressing greatly reduced levels of the isoenzyme lipoxygenase-1 for the production of flavor-stable beverage. Douma et al also teach barley varieties whose developing and germinating grain produces greatly reduced LOX-1 activity, and methods for producing said varieties. The cited reference also teaches methods for screening and selecting lipoxygenase mutants from mutagenized barley plants. Douma teaches methods for targeting Lox-1 gene in barley and parts thereof by site directed mutagenesis, by chimeric RNA/DNA, and by antisense expression or by chemical mutagenesis. Douma also teaches methods of confirming loss of Lox-1 activity in putative mutants. Figure 13 of Douma et al shows the LOX-1 gene of wild-type and the mutant lox-1, which shows two mutations in LOX-1 gene (see the whole documents). While Douma et al do not explicitly teach barley plants comprising less than 5% or 1% LOX-1 activity of a wiltype barley, one would have a reasonable expectation of success to achieve such 5% or 1% level of LOX-1 activity by using the various methods including the site- directed mutagenesis, antisense expression, or by chemical mutagenesis disclosed by Douma et al.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent

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and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-14 and 48-49 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,660,915. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in both the application and the issued patent are drawn to barley plants or parts thereof with greatly reduced LOX-1 activity as compared to a wildtype-barley plant, and methods for producing said plants and plant parts. The claims of the application are drawn to barley plants and parts thereof including embryo or kernel comprising less than 5% or 1% of the Lox-1 activity of a wildtype barley plant, barley plants comprising mutation in a specific LOX-1 sequence, and plants deposited under ATCC accession number, which encompass the barley plants characterized by absence of LOX-1 activity by comprising LOX-sequence with specified point mutations. While Douma et al do not explicitly teach barley plants comprising less than 5% or 1% LOX-1 activity of a wiltype barley, one would have a

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reasonable expectation of success to achieve such 5% or 1% level of LOX-1 activity by using the various methods including the site- directed mutagenesis, antisense expression, or by chemical mutagenesis known in the art. Therefore, the invention claimed in the application would have been obvious over the invention claimed in the issued patent.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (571) 272-0797. The Examiner can normally be reached Monday -Thursday from 8:00AM to 5:30PM and every other Friday from 9:00AM to 5:00 PM . Before and after final responses should be directed to fax nos. (703) 872-9306 and (703) 872-9307, respectively.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Anne Marie Grunberg, can be reached at (571) 272-0975.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

10/16/06

Mai

MEDINA A. IBRAHIM
PRIMARY EXAMINER

